July 27, 2020

Control Medical Technology, LLC
℅ Mark Job
Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K131998
Trade/Device Name: Aspire Rx-LP6 Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Mark Job:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 26, 2013. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2020.07.27 08:17:26 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Control Medical Technology, LLC
c/o Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, MN 55313

Re: K131998
Trade/Device Name: ASPIRE RX-LP6 Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: October 29, 2013
Received: October 30, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. Indication for Use Statement

510(k) Number: _K131998_____

Device Name: Aspire RX-LP6 Aspiration Catheter

Indications for Use:

The Aspire RX-LP6 Aspiration Catheter and Aspirator are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

| | | | |
|---|---|---|---|
| Prescription Use (Part 21 CFR 801 Subpart D) | X | AND/OR | Over-The-Counter Use ___ (21 CFR 807 Subpart C) |

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

## 5. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

**Date Summary was Prepared**

November 19, 2013

**Submitter**

Control Medical Technology
136 Heber Avenue, Suite 101
PO Box 681013
Park City, UT 84068
Phone (954) 534-9345

**FDA Establishment Registration Number**

3007282893

**Contact**

President
Control Medical Technology
136 Heber Avenue, Suite 101
PO Box 681013
Park City, UT 84068
Phone (954) 534-9345

**Device Information**

| | |
|---|---|
| Trade Name: | Aspire RX-LP6 Aspiration Catheter |
| Common Name: | Embolectomy or aspiration catheter and aspirator |
| Classification Name: | Embolectomy catheter |
| Product Code: | DXE |
| Regulation: | Class II, 21 CFR 870.5150 |

**Predicate Devices**

Aspire RX-LP6 Aspiration Catheters are substantially equivalent to the Medtronic Export Aspiration Catheters, Vascular Solutions Pronto Extraction Catheters, Lumen – Volcano Xtract Aspiration Catheters, and other predicate devices.

| | |
|---|---|
| Trade Names: | Xpress-Way RX Catheter K121301 July 30, 2012<br>Export XT Aspiration Catheters K061958 September 5, 2006<br>Pronto V3 Aspiration Catheter K063371 Mar 30, 2009 |
| Common Name: | Embolectomy or aspiration catheter and piston syringe |
| Classification Name: | Embolectomy catheter |
| Product Code: | DXE |
| Regulation: | Class II, 21 CFR 870.5150 |

**Device Description**

An "Aspire RX-LP6 Aspiration Catheter" includes (1) RX-LP6 Aspiration Catheter and (1) Aspire Aspirator 30ml.

- Aspire RX-LP6 Aspiration Catheters (RX-LP6 Aspiration Catheter and Aspire Aspirator): 6F Guide Cath compatible rapid exchange catheter with 4.8mm long distal aspiration opening, 1.0mm wide distal and 1.1mm wide proximal aspiration lumen, 0.054" outer diameter (OD) single lumen aspiration shaft, and removable stylet.
- Aspire Aspirator 30ml.

Aspire RX-LP6 Aspiration Catheters are single-use, sterile, short-term use, and non-pyrogenic medical devices designed for use with piston syringes to remove fresh, soft emboli and thrombi from the peripheral and coronary vasculature. The Aspire RX-LP6 Aspiration Catheter operating and scientific principle is the same as predicate devices. The catheter is inserted into the body over a guidewire and through a sheath or guide catheter to the target anatomy. A syringe is then connected to the catheter and the aspiration is manually created with the syringe.

Similar to predicate devices, industry standard intravascular catheter components and materials are used:

- Clear proximal polycarbonate female luer lock,
- Stainless steel core wire,
- Clear Main Shafts,
- Embedded platinum iridium radiopaque marker,
- Clear polycarbonate barrel piston syringe.

Aspire RX-LP6 Aspiration Catheters do not add any new materials, or manufacturing processes to the manufacturing process.

Same as predicates, all RX-LP6 Aspiration Catheters may be may be connected to piston syringes including the Aspire Mechanical Aspirator. Aspire Aspirators may be connected to other catheters to aspirate fluids and thrombus.

**Indications, Intended Use and Contraindications**

Indication: "The Aspire RX-LP6 Aspiration Catheter and Aspirator are indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature."

Intended Use: Aspire RX-LP6 Aspiration Catheters are single-use devices intended for use by physician's experienced and trained in diagnostic and interventional procedures. Techniques for placement of vascular sheaths, catheters, and guidewires may be used.

Contraindications: "The RX-LP6 Aspiration Catheter is contraindicated in: vessels < 2mm in diameter, the removal of fibrous, adherent or calcified material (e.g., chronic clot, atherosclerotic plaque), the venous system, and cerebral vasculature."

The indication and intended use is substantially equivalent other thrombus aspiration catheters manually actuated by syringes and legally marketed under the DXE product code.

**Comparison to Predicate Devices**

Aspire RX-LP6 Aspiration Catheters and Aspire Aspirator are substantially equivalent to predicate devices used to remove fresh, soft thrombi/emboli. Substantial equivalence is based on equivalence in:

| | |
|---|---|
| **Science** | |
| Scientific Principle | Mechanism of Use |
| **Device Construction** | |
| Design & Dimensions | Manual Use |
| Function | Piston Syringe Driven Aspiration |
| Materials | Manufacturing |
| **Device Performance** | |
| Aspiration | Bend & Torque |
| Break strength integrity | Tracking |
| Freedom of Leakage Injection | Freedom from Leakage Aspiration |
| **Labeling** | |
| Indication for Use & Intended Use | Contraindications |
| Warnings | Instructions for Use |
| **Manufacturing** | |
| Biocompatibility | Sterilization |

**New device is compared to predicate device?** Yes, Aspire RX-LP6 Aspiration Catheters are compared to the predicates against predetermined metrics and performance test criteria.

**Does the new device have the same indication for use as predicate device?** Yes. The Xpress-Way predicate adds that the device is not intended for neurovascular use in the instruction for use. The subject device and other predicates include neurovascular use as a contraindication.

**Do the differences between the new device and predicate alter the intended therapeutic or diagnostic effect as predicate device?** No, the differences between Aspire RX-LP6 Aspiration Catheters and predicates do not alter the intended use of the device.

**Does the new device have the same technical characteristics, materials, manufacturing processes as predicate?** Yes, the Aspire RX-LP6 Aspiration Catheter's manually operated aspiration principle of operation and technical characteristics are the same as predicates. Aspire RX-LP6 Aspiration Catheters and piston syringe materials including but not limited to Pebax shafts; luer lock hubs; and polycarbonate piston syringe barrels the same as predicates. The RX-LP6 and all predicates are configured as rapid exchange catheters. The RX-LP6's rapid exchange length is in between the shortest and longest predicates (Xpress-Way's rapid exchange length is 2cm and the Pronto is 20cm). Manufacturing extrusion, molding, and assembly in ISO 14644 Class 8 certified clean room is the same as predicates. No new materials or manufacturing processes.

**Could the new characteristics affect safety?** No.

**Do new characteristics raise new types of safety and effectiveness questions?** No.

**Do accepted scientific methods exist for assessing effects of new characteristics?** Yes, testing was based on FDA recognized standards and guidance including but not limited to:

- ISO 10555-1:1997 Sterile, Single-Use, Intravascular Catheters.
- ISO 7886-1:1993(E) Sterile Hypodermic Syringe s for Single Use.
- AAMI/ANSI/ISO 11135:1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization.

**Non-Clinical Testing**

Non-clinical testing confirms the Aspire RX-LP6 Aspiration Catheters and Aspirator passes all testing and meets specifications. Specific tests confirm functionality in the intended use, safety, demonstration of claims, and equivalence to predicate devices plus compliance with ISO recognized standards.

A. General:
   - Visual and surface inspection,
   - Corrosion resistance testing,
   - Dimensional inspection.

B. Integrity and compatibility:
   - Guidewire compatibility testing,
   - Catheter radiopacity testing,
   - Catheter force at break catheter tensile strength integrity testing,
   - Catheter force at break bonds tensile strength integrity testing,
   - Catheter kink testing,
   - Catheter torque testing,
   - Catheter tracking simulated anatomy testing as part of aspiration testing.

C. Aspiration testing:
   - RX-LP6 Aspiration Catheters and predicates with low viscosity aspirants,
   - RX-LP6 Aspiration Catheters and predicates with high viscosity aspirants,
   - Blood aspiration,
   - Thrombus aspiration,
   - In-vivo aspiration.

D. Biocompatibility:
   - Cytotoxicity Minimal Essential Media (MDM) Elution ANSI/AAMI/ISO 10993-5
   - Acute Systemic Toxicity ISO 10993-11
   - Pyrogen Material Mediated USP <151>
   - LAL Endotoxin Test USP <85>
   - Intracutaneous Reactivity ISO 10993-10
   - Maximization Sensitization Test ISO 10993-10
   - Hemocompatibility Hemolysis ASTM Direct Contact ISO 10993-4

   Subject devices passed all biocompatible tests.

E. Particulate: Validated particulate testing confirmed subject devices passed with scores significantly below an established minimum national standard.

**Clinical testing**
Not applicable.

**Statement of Equivalence**
Aspire RX-LP6 Aspiration Catheters are substantially equivalent to the currently marketed Pronto, Export, and Xpress-Way aspiration systems based on comparison of the device classification, basic operating principle, indication for use, intended use, technical characteristics, packaging, and sterilization methods.

**Conclusion**
Aspire RX-LP6 Aspiration Catheters are substantially equivalent to the currently marketed Pronto, Export, and Xtract catheters based on comparison of the device classification, basic operating principle, indication for use, intended use, technical characteristics, packaging, and sterilization methods. Testing confirms the suitability of Aspire RX-LP6 Aspiration Catheters and Aspirator for its intended use.

The conclusions drawn from the nonclinical tests that demonstrate that Aspire RX-LP6 Aspiration Catheters is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified as predicated devices in this section.